K013762

APR 0 3 2002

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B) AND BOSTON® XO (hexafocon A) RIGID GAS PERMEABLE CONTACT LENSES

1. SUBMITTER INFORMATION

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609

Contact Person: Debra Ketchum
Manager, Regulatory Affairs
Telephone No.: (585) 338-8638

2. DEVICE NAME

Classification Name: rigid gas permeable (hydrophobic) contact lens

Proprietary Name: BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B), and BOSTON® XO (hexafocon A) Rigid Gas Permeable Contact Lenses

3. PREDICATE DEVICE

The BOSTON® II (itafocon A) Rigid Gas Permeable Contact Lens approved in Premarket Application, P820065, on November 17, 1983, has been selected as the predicate device for the BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B), and BOSTON® XO (hexafocon A) Rigid Gas Permeable Contact Lenses.

4. DESCRIPTION OF DEVICE

The BOSTON ES® (enflufocon A) and BOSTON EO® (enflufocon B) are Rigid Gas Permeable Contact Lens materials composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer with an ultraviolet absorber.

BOSTON® XO (hexafocon A) is a rigid gas permeable contact lens material, composed of siloxanyl fluoromethacrylate copolymer containing an ultraviolet absorber.

The color additives conform to 21 CFR Part 74 and/or 21 CFR Part 73. The lens may also be supplied clear (no tint).

The physical / optical properties of the lens are:

Property	BOSTON ES	BOSTON EO	BOSTON XO
Specific Gravity	1.22	1.23	1.27
Refractive Index	1.443	1.429	1.415
Light Transmittance	C.I.E. Y value - at least %	C.I.E. Y value - at least %	C.I.E. Y value - at least 92%
Water Content	<1%	<1%	<1%
Oxygen Permeability (Dk)	36* 18**	82* 58**	140* 100**

*gas to gas
**ISO/Fatt

5. INDICATIONS FOR USE

The BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B) and BOSTON® XO (hexafocon A) Rigid Gas Permeable Contact Lenses are indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, astigmatism, presbyopia and keratoconus) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be disinfected using a chemical disinfection system only.

6. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE

The safety and efficacy of BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B) and BOSTON® XO (hexafocon A) Rigid Gas PermeableContact Lenses was demonstrated in 510(k) Premarket Notifications: K943177 cleared on August 25, 1994; K980741 cleared on May 11, 1998; and K000795 cleared on May 25, 2000, respectively.

BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B) and BOSTON® XO (hexafocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to BOSTON II (itafocon A) Rigid Gas Permeable Contact Lenses approved in Premarket Application, P820065, on November 17, 1983 including an indication for keratoconus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Debra Ketchum
Bausch and Lomb Inc.
1400 N. Goodman St.
Rochester, NY 14609

APR 0 3 2002

Re: K013762
Trade/Device Name: Boston ES® (enflufocon A), Boston EO® (enflufocon B) and Boston® XO (hexafocon A) Rigid Gas Permeable Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: February 28, 2002
Received: March 1, 2002

Dear Ms. Ketchum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

Indications for Use Statement

510(k) Number (if known): K013762

Device Name: BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B) AND BOSTON® XO (hexafocon A) RIGID GAS PERMEABLE CONTACT LENSES

Indications for Use:

The BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B) and BOSTON® XO (hexafocon A) Rigid Gas Permeable Contact Lenses are indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, astigmatism, presbyopia and keratoconus) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be disinfected using a chemical disinfection system only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____

Myra Smith
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(K) Number K013762